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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/721,183	11/22/00	SALCEDA S	DEX-0117

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HM12/0615

EXAMINER	
DAVIS,N	
ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/721,183	SALCEDA ET AL.	
	Examiner	Art Unit	
	Natalie A Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 8-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1(a), (c) (in part, as it reads on polynucleotides), drawn to a BCSG comprising a polynucleotide, classified in class 536, subclass 23.1.

II. Claims 1 (b), and 2, (in part, as it reads on proteins), drawn to a BCSG comprising a protein, classified in class 530, subclass 350.

III. Claims 3-7, drawn to a method of diagnosing, staging, and monitoring breast cancer, classified in class 435, subclass 4.

IV. Claim 8, drawn to a method of identifying potential therapeutic agents, classified in class 435, subclass 7.1.

V. Claims 9-10, drawn to an antibody, which binds BCSG, classified in class 424, subclass 138.1.

VI. Claims 11-12, drawn to a method of imaging breast cancer, classified in class 424, subclass 9.3.

VII. Claims 13-15, drawn to a method of treating breast cancer, classified in class 424, subclass 183.1.

VIII. Claim 16, drawn to a method of inducing an immune response, classified in class 424, subclass 184.1.

IX. Claim 17, drawn to a vaccine, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II, V (products) and III-IV, VI-VIII (methods) are related as apparatus and product made. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case the products of Groups I-II, V

may be used for a number of different processes that are very much unrelated. For example, the antibody of Group V may not only be used for affinity purification. Likewise, the method of VII may be practiced using various therapeutic agents such as Tamoxifen.

3. Inventions I-II, V are structurally and functionally different from one another. The polynucleotides of Group I can be used to make the peptides of Group II but the peptides can be extracted directly from cells and do not have to be derived from the sequences of Group I. The polynucleotides of Group I can be used directly for immunization and not just for making the peptide. The inventions of Groups II and V do not have to be used with one another, as a different cross-reacting antibody may be directed towards the peptide sequence of Group II. The antibody may be isolated from plasma or affinity chromatography and not necessarily prepared using the peptide sequence of Group II.

4. The inventions of Groups III-IV, VI-VIII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and require different search strategies, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Attorney Tyrrell on 29 May a provisional election was made with traverse to prosecute the invention of Group II, claims 3-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-2 and 8-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement filed 22 November, 2000 has been considered. A signed copy is attached hereto.

Specification

8. The abstract of the disclosure is objected to because it is not in compliance with Rule 37 CFR 1.72(b). The content of a patent abstract should be such as to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to ascertain quickly the character of the subject matter covered by the technical disclosure and should include that which is new in the art to which the invention pertains. The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 250 words. Correction is required. See MPEP § 608.01(b).

9. The use of the trademark TAQMAN® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of "BCSG" without delineation of the full name of the entity, which the abbreviation denotes, is indefinite. For purposes of clarification it is suggested that the claims be amended at the first occurrence of the abbreviation to recite the full name "Breast Cancer Specific Genes."

12. Claims 3-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..." The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles," a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method of diagnosing the presence of breast cancer and metastasis thereof, in addition to the staging and monitoring for the onset of metastasis and stage changes, wherein the expression levels of BCSG in cells, tissues, or bodily fluids in a patient as compared to expression levels in normal human control samples.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that breast cancer may be diagnosed by detecting changes such as the over/underexpression, and/or mutation of specific genes such as BRAC1, BRAC2, and p53. The art also, teaches that the detection of quantitative changes in the expression of genes differentially expressed in breast cancer may be used as novel molecular markers, which may be useful in the diagnosis and treatment of breast cancer (Ji et al., WO 98/33915). Ji et al., teach the diagnosis of breast cancer by overexpression of BCSG1 in cancerous tissue as compared to expression in normal and benign tissue (no BCSG expression in normal or benign tissue). Ji et al., also teach gradient and stage-specific BCSG1 expression from virtually no detectable expression in normal or benign breast tissue to the low level and partial expression in the low grade in situ breast carcinoma and to the high expression in the infiltrating malignant or breast carcinoma. Based on the teachings in the art, in order for breast cancer to be diagnosed, it must be certain that changes in the expression levels of BCSG as compared to levels in normal breast is indeed indicative of breast cancer and not some other disease. Furthermore, the predictability of determining cancer or metastasis thereof in cells, tissue, or bodily fluids that are from the breast is uncertain because the prior art has only taught the diagnosis of cancer by determining the expression of BCSG in breast tissue alone.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order for the skilled artisan to diagnose, stage and monitor breast cancer as claimed. These teachings are not present. While the specification discloses that BCSG-2 is expressed primarily in mammary gland tissue, it fails to disclose any definitive evidence that shows a correlation between measured levels and cancer. The levels BCSG in cancer tissue is elevated, reduced, and not statistically different, when compared to

normal tissue (Table 7). In addition, the results in Table 3 are inconclusive and the claims encompass measuring BCSG levels in tissue other than breast and the specification discloses that the gene is expressed in breast only.

The breadth of the claims and the quantity of experimentation needed: Since the art teaches that BCSG1 expression is associated with breast cancer and that the expression levels were determined in breast tissue alone, it would be extremely unpredictable to diagnose, monitor, and stage breast cancer or metastasis by determining the levels of BCSG in cells, tissues, or bodily fluids in a patient, unless these samples are from breast tissue and that the levels clearly correlated with the presence of breast. Thus, one ordinary skilled in the art would be forced into undue experimentation to practice the invention as claimed.

Conclusion

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, Ph.D.
June 14, 2001

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER